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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bernhard Gleich

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS

P.O. BOX 3001

BRIARCLIFF MANOR, NY 10510

EXAMINER

MEHTA, PARIKHA SOLANKI

ART UNIT

PAPER NUMBER

3737

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,819	<b>Applicant(s)</b> GLEICH ET AL.	
	<b>Examiner</b> PARIKHA S. MEHTA	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/25/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Requirement for Additional Information***

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. It appears that Applicant has a large number of pending and patented applications including claims directed towards methods of examining a subject including the steps of 1) generation of a magnetic field with a first sub-area having a low magnetic field strength and a second sub-area having a high magnetic field strength, 2) change of the spatial position of the sub-areas to induce a change in local particle magnetization, 3) acquisition of signals dependent on particle magnetization in the area of examination, and 4) evaluation of the signals to obtain information about a change in spatial distribution or a movement of magnetic particles within the examination area. The examiner has recognized herein three conflicting patents and/or applications which present double-patenting issues; however, for the sake of expediting prosecution, Applicant is required to identify any remaining pending or patented applications that claim methods having the same or similar steps.

### ***Specification***

2. The abstract of the disclosure is objected to because its length exceeds 150 words. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “the spatial distribution”, “the magnetic field strength”, “the particularly relative spatial position”, “the magnetization of the particles”, “the magnetization in the area”, “the change in spatial distribution,” and “the movement” without sufficient antecedent basis.

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In claim 1, it is unclear what definitive limitation is set forth by “especially diluted”, “especially, a thin coating”, and “especially liquid”.

In claim 3, it is unclear what structural limitation is set forth by “represent”.

Claim 4 recites “the lungs, sinuses or other parts”, “the breathing system”, “the digestive system, inner ears, bladder, vagina, mammary glands, circulation system”, and “the heart, liver, spleen, lymph system, bone marrow” without sufficient antecedent basis.

In claim 4, it is unclear what limitations are set forth by “especially” and “particularly”.

In claim 5, it is unclear what definitive limitation is set forth by “may comprise”.

In claim 7, it is unclear what definitive limitation is set forth by “especially”.

In claims 9-12, the term “the magnetic particle” lacks clear antecedent basis, as claim 1 sets forth multiple magnetic particles.

Claim 12 recites “the hard magnetic materials” without sufficient antecedent basis. For the purposes of further examination herein, claim 12 will be treated as depending from claim 11.

Claim 13 recites “the material used for encasing or coating” without sufficient antecedent basis.

In claim 13, it is unclear what limitation is set forth by “can be”.

It is unclear whether the recitation “means of” in claim 13 is intended to invoke 35 U.S.C. 112, 6<sup>th</sup> paragraph. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

(a) Amend the claim to include the phrase “means for” or “step for” in accordance with these guidelines: the phrase “means for” or “step for” must be modified by functional language and the phrase must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Show that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr (US Patent No. 6,470,220), hereinafter Kraus, Jr. ('220).

**Regarding claims 1-3, 8 and 13**, Kraus, Jr. ('220) teaches a method of generating a magnetic field having a "relatively uniform" field strength, wherein "relatively uniform" is interpreted as meaning "not perfectly uniform", i.e. the field must implicitly have a first sub-area of lower field strength and a second sub-area of higher strength (col. 13 lines 20-22). Kraus, Jr. ('220) goes on to teach changing the spatial position of the field, which includes the two sub-areas, so that a magnetization of administered particles changes locally, acquiring signals depending on such magnetization, and evaluating the acquired signals to obtain information about the change in spatial distribution of the particles (col. 13 lines 9-32). Kraus, Jr ('220) teaches the particles as being introduced into the examination area in the form of particles having a biochemically-degradable coating (col. 12 line 59 – col. 13 line 5). The particles of Kraus, Jr. ('220) are considered to be at least partly anisotropic in that their rotation varies when measured in different directions.

**Regarding claims 4 and 7**, Kraus, Jr. ('220) teaches applying the reference method to an examination area including mammary glands of an organism (col. 3 lines 33-44, teaching of application for breast cancer).

**Regarding claim 5**, although Kraus, Jr. ('220) does not expressly teach applying the reference method to examination of a material having boreholes or a material made of plastic or ceramic, or a material comprising a polymer, it is well known in the art that these are features of artificial tissue phantoms commonly used to test imaging methods. Accordingly, it would have been obvious to a skilled artisan to have performed the method of Kraus, Jr. ('220) on an examination area including a tissue phantom comprising boreholes, plastic or ceramic materials, in order to test the efficacy of the reference imaging method prior to applying it to a living subject. Alternatively, since the claim recites that the

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boreholes, plastic and ceramic “may be” part of the examination area, the claim can be interpreted as not requiring the feature, in which case the reference meets the claim without modification.

**Regarding claim 6**, Kraus, Jr. ('220) teaches rotating the field through multiple positions, which constitutes repeating steps b) through d) as claimed (col. 13 lines 33-62).

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr. ('220) as previously applied to claim 1, further in view of Ivkov (US PG Pubs. No. 2006/0142749). Kraus, Jr. ('220) does not expressly teach the particles to be mono-domain particles which are magnetically reversed through Brownian or Neel rotation. In the same problem solving area, Ivkov ('749) teaches a method of examining a patient including the step of administering monodomain magnetic particles configured to be reversed via Neel rotation (§§ 15, 16, 22, 27, 63-64). It would have been obvious to a skilled artisan to have tried to use the particles of Ivkov ('749) with the method of Kraus ('220) and to thereby yield the claimed invention, as both references are directed towards tracking and treating tumors (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr. ('220) as previously applied to claim 1, further in view of Rand (US PG Pubs. No. 2005/00669610), hereinafter Rand ('610). Kraus, Jr. ('220) does not teach the particles as being hard or soft magnetic multi-domain particles. In the same problem solving area, Rand ('961) teaches a method of magnetic imaging of an examination area including the step of administering soft, multi-domain magnetic contrast particles (§ 10). It would have been obvious to a skilled artisan to have tried to use the particles of Rand ('610) in the method of Kraus ('220) and to thereby yield the claimed invention, as both references are directed towards tracking and treating tumors (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

10. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr. ('220) as previously applied to claim 1, further in view of Frei et al (US Patent No. 3,592,185), hereinafter Frei ('185). Kraus, Jr. ('220) does not expressly teach the magnetic particles as comprising hard magnetic particles such as Al-Ni, Al-Ni-Co, Fe-Co-V, or barium ferrite. In the same field of endeavor of magnetic contrast imaging, Frei ('185) teaches use of barium ferrite as a particle contrast agent. It would have been obvious to one of ordinary skill in the art at the time of invention to have performed the method of Kraus, Jr. ('220) using barium ferrite as taught by Frei ('185) for the magnetic

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particles, as such a combination of known prior art steps to yield predictable results has previously been held as obvious and unpatentable (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 3, 9, 10, 11 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 20, 21 and 25 of copending Application No. 10/552,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims merely recite the additional limitations placed upon the form of the magnetic particles when they are introduced into the examination area. All particle forms recited by claim 1 are described in the co-pending specification, such that a skilled artisan would have found it obvious to have performed the conflicting method by using particles having one of those forms. Furthermore, magnetic particles of suspension, aerosol, powder, coated, capsule, coupled, or liquid forms are well known in the art, and as

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such a skilled artisan would be reasonably motivated to perform the conflicting method using particles having any of the forms known in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1, 3, 9, 10, 11 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10 and 11 of copending Application No. 10/552,806. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims merely recite the additional limitations placed upon the form of the magnetic particles when they are introduced into the examination area. All particle forms recited by claim 1 are described in the co-pending specification, such that a skilled artisan would have found it obvious to have performed the conflicting method by using particles having one of those forms. Furthermore, magnetic particles of suspension, aerosol, powder, coated, capsule, coupled, or liquid forms are well known in the art, and as such a skilled artisan would be reasonably motivated to perform the conflicting method using particles having any of the forms known in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1, 3, 9, 10, 11 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of US Patent No. 7,778,681. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims merely recite additional limitations placed upon the form of the magnetic particles when they are introduced into the examination area. Magnetic particles of suspension, aerosol, powder, coated, capsule, coupled, or liquid forms are well known in the art, and as such a skilled artisan would be reasonably motivated to perform the conflicting method using particles having any of the forms known in the art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8:00 am - 4:30 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Parikha S Mehta/  
Examiner, Art Unit 3737